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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/284,297 07/05/00 LSE

EXAMINER
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HM22/0523

MARY ROSE SCOZZAFAVA  
CLARK & ELBING  
176 FEDERAL STREET  
BOSTON MA 02110

ART. UNIT	PAPER NUMBER
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DATE MAILED:

05/23/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3/5/01

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 40, 42, 43, 103, 111-148 is/are pending in the application.  
Of the above, claim(s) 121, 135, 146 is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 40, 42, 43, 103, 111-120, 122-134, 136-145, 147-148 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☒ Claim(s) 40, 42, 43, 103, 111-148 are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1616

Applicant's election without traverse of bone protein and demineralized bone in Paper No. 15 is acknowledged.

Claims 121, 135 and 146 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 15.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 or 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 42, 43, 103, 111-120, 122-134, 136-145, 147 and 148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1616

“Compact”, “Promoter”, “Predetermined”, “Strongly”, “Poorly”, “intimate”, “supplemental”, “selected”, “characteristic” are all indefinite, ambiguous or relative terms, and fail to impart specificity to permit identification of the meets and bounds of the subject matter of the invention as it is claimed. So is “suitable”, “associated with”, “derivativized”. There is no antecedent for “conversion” of claim 111.

Claims 40, 42, 43, 103, 111-120, 122-134, 136-143, 145, 147, 148 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. One of ordinary skill in the bioceramic arts would not know how and what to prepare and under what condition, in order to arrive at the claimed, poorly identified, compositions, composites and method. It is not clear how pressing is done in vivo (claim 113).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Art Unit: 1616

Claims 40, 42, 43, 103, 111-114, 116-118, 120, 122, 124, 126-131, 133, 134, 136, 138-145, 147, 148 are rejected under 35 U.S.C. 102(e) as being anticipated by Constantz et al 5782971.

See claim 1; the compositions of the instant invention, as of instant claims 42, 43. Instant 111, 114, 116-118, 120, 122, 124, 126-131, 133, 134, 136, 138-145, 147 and 148 are encompassed, as the materials of the instant claims are present, prepared in the instant manner, thus inherently providing the instant characteristics--These are shown at Constantz claims 1-4, 7-20, and, for (claim 40) pressing and mixing, at Col. 8, B. for incubation at 37° (claim 112) at col. 8; III, A. In vivo application is presented at Col. 9, line 30-43, summary and col. 6, bottom. Bioactives are at col. 5 and 6. The x-ray diffraction is a function of the conversion to hydroxyapatite--inherently it would be seen--see claim 16 - 18. The same ingredients and procedures are performed and provided as is INSTANTLY claimed, thus, the same aspects, characteristics and functions would inherently be present.

Claims 40, 42, 43, 103, 111-114, 116-120, 122-134, 136-145, 147, 148 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Constantz 4880610.

Constantz teaches one can utilize either endothermic, exothermic or no change in mix temperature (col. 3, top), as desired. Also disclosed are amorphous, or crystalline polyphosphoric compounds, prepared dry or as liquids. Ca/P of hydroxy apatite is taught, as the ratio to be achieved (paragraph 2). PH is shown as 5-9 (paragraph 4). Ground bone, collagen,

Art Unit: 1616

morphogenetic protein maybe incorporated (col. 4). Mixing, shaping and packing is taught (col. 5) DCPD is disclosed at Example 1, as are x-ray diffraction analyses similar to the instant. The desired amount of hydroxy apatite will be determined by the artisan, and thus determine the X-ray pattern (col. 6, lines 10-50). Example 2 shows rat implantation, thus, the same characteristics as are instantly claimed would be evident as expected results of the same process as of the instant invention.

Claims 40, 42, 43, 103, 111-119, 120, 122-134, 136-145, 147, 148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al 5782971 in view of Constantz 4880610 and Fukase et al '90.

Constantz, '578 (above) discloses paste compositions and bioceramic composites and preparation as of the instant invention used in the instant methods, but does not encompass all of the forms. The mechanisms of action are not fully presented. Constantz, however, teaches one can utilize either endothermic, exothermic or no change in mix temperature (col. 3, top), as desired. Also disclosed are amorphous or crystalline polyphosphoric compounds, prepared dry or as liquids. Ca/P of hydroxy apatite is taught, as the ratio to be achieved (paragraph 2). PH is shown as 5-9 (paragraph 4). Ground bone, collagen, morphogenetic protein maybe incorporated (col. 4). Mixing shaping and packing is taught (col. 5) DCPD is disclosed at Example 1, as are X-ray diffraction analyses similar to the instant. The desired amount of hydroxy apatite will be determined by the artisan, and thus determine the X-ray pattern (col. 6, line 10-50). Example 2 shows rat implantation, thus, the same characteristics would be expected as are instantly claimed.

Art Unit: 1616

Lyophilization is shown by Fukase (summary) as well with in the skill of one in the bioceramic arts to accomplish.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an effective, stable bone treatment composition to utilize Constantz with improvements as taught by Constantz et al, of artisans choice, while Fukase further teaches one having ordinary skill in the art would be motivated to perform this modification in order to achieve greater stability, ease of handling, and action, and strength of the bone compositions.

There is no unusual and/or unexpected results obtained since the prior art is well aware of the use of specific Ca/P sources, bioactives, carriers promotes and other adjuvants common to the art as means of bone repair and the use ingredients for the functionality for which they are known to be used is not a basis for patentability.

Claims 40, 42, 43, 111-120, 126-134, 138-145, 148 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al 6201039 B1.

See summary, Examples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday to Friday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Application/Control Number: 09/284,297

Page 7

Art Unit: 1616

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Levy:mv

May 18, 2001

A handwritten signature in black ink, appearing to read "Neil S. Levy", is written over the end of the paragraph.

**NEIL S. LEVY**  
**PRIMARY EXAMINER**